

(Published in Part II, Section 3, Sub-section (ii) of the Gazette of India, Extraordinary)

Government of India

Ministry of Chemicals and Fertilizers

Department of Pharmaceuticals

National Pharmaceutical Pricing Authority

New Delhi, the 30th March, 2017

ORDER

S.O. 1010(E) In implementation of directions given in line with review orders issued by the Department of Pharmaceuticals (DOP) vide letters no. 31015/18/2016-PI.I dated 30.8.2016 (Tacrolimus Capsule 0.5mg & 1mg), 31015/58/2016-PI.I dated 06.10.2016 (Phenytoin Tablet 100mg), 31015/29/2016-PI.I dated 30.8.2016 (Azithromycin Tablet 500mg & 250mg), 31015/26/2016-PI.I dated 30.8.2016 (Rifampicin Capsule 150mg, 300mg, 450mg & Rifampicin Syrup 100mg/5ml) & 31015/85/2016-PI.I dated 15.11.2016 (Imatinib Mesylate Tablet 100mg) respectively passed by the Department of Pharmaceuticals and in exercise of the powers conferred by paragraphs 4, 10, 11, 14, 16, 17 and 18 of the Drugs (Prices Control) Order, 2013, read with S.O. 1394(E) dated the 30th May, 2013 and S.O. 701(E) dated 10th March, 2016 issued by the Government of India in the Ministry of Chemicals and Fertilizers, and in supersession of the Order of the Government of India in the Ministry of Chemicals and Fertilizers (National Pharmaceutical Pricing Authority) No. S.O. 1404(E), dated 12th April, 2016 at Sl. No. 64 & 65 (Tacrolimus Capsule 0.5mg & 1mg), S.O. 1819(E) dated 18th May, 2016 at Sl. No. 6 (Phenytoin Tablet 100mg), S.O. 1686(E) dated 9th May, 2016 at Sl. No. 4 & 5 (Azithromycin Tablet 500mg & 250mg), S.O. 2730(E) dated 17th August, 2016 at Sl. No. 9, 10 & 11 (Rifampicin Capsule 150mg, 300mg & 450mg), S.O. 248(E) dated 24th January, 2017 at Sl. No. 11 (Rifampicin Oral Liquid 100mg/5ml) & S.O. 2730(E) dated 17th August, 2016 at Sl. No. 13 (Imatinib Mesylate Tablet 100mg) respectively regarding formulation pack mentioned in the table in so far as it relates to formulation pack mentioned in the table below, except in respect of things done or omitted to be done before such supersession, the National Pharmaceutical Pricing Authority, hereby fixes the price as specified in column (5) of the table herein below as ceiling price exclusive of local tax applicable, if any in respect of the Scheduled formulation specified in the corresponding entry in column (2) of the said Table with the dosage form & strength and unit specified respectively in the corresponding entries in columns (3) and (4) thereof:

TABLE

Sl. No.	Name of the Scheduled Formulation	Dosage form & Strength	Unit	Ceiling Price (Rs.)
(1)	(2)	(3)	(4)	(5)
1.	Tacrolimus	Capsule 0.5mg	1 Capsule	20.92
2.	Tacrolimus	Capsule 1mg	1 Capsule	36.96
3.	Phenytoin	Tablet 100mg	1 Tablet	1.47
4.	Azithromycin	Tablet 500mg	1 Tablet	18.82
5.	Azithromycin	Tablet 250mg	1 Tablet	9.28
6.	Rifampicin	Capsule 150mg	1 Capsule	1.90
7.	Rifampicin	Capsule 300mg	1 Capsule	3.60
8.	Rifampicin	Capsule 450mg	1 Capsule	4.67

9.	Rifampicin	Oral Liquid 100mg/5ml	1 ML	0.37
10.	Imatinib	Tablet 100mg	1 Tablet	75.15

Note:

- (a) The ceiling prices are applicable with effect from 01.4.2017 (ceiling prices are inclusive of Wholesale Price Index (WPI) @1.97186% for the year 2016 over 2015).
- (b) All manufacturers of scheduled formulations, selling the branded or generic or both the versions of scheduled formulations at a price higher than the ceiling price (plus local taxes as applicable) so fixed and notified by the Government, shall revise the prices of all such formulations downward not exceeding the ceiling price specified in column (5) in the above table plus local taxes as applicable, if any.
- (c) All the existing manufacturers of above mentioned scheduled formulations having MRP lower than the ceiling price specified in column (5) in the above table (plus local taxes as applicable, if any), may revise the existing M.R.P. of their formulations, on the basis of WPI @ 1.97186% for year 2016 in accordance with paragraph 16(2) of DPCO, 2013, subject to ceiling price (plus local taxes as applicable, if any).
- (d) The manufacturers may add local taxes only if they have paid actually or if it is payable to the Government on the ceiling price mentioned in column (5) of the above said table.
- (e) The ceiling price for a pack of the scheduled formulation shall be arrived at by the concerned manufacturer in accordance with the ceiling price specified in column (5) of the above table as per provisions contained in paragraph 11 of the Drugs (Prices Control) Order, 2013. The manufacturer shall issue a price list in Form-V from date of Notification as per paragraph 24 of the DPCO, 2013 to NPPA through IPDMS and submit a copy to State Drug Controller and dealers.
- (f) As per para 24(4) of DPCO 2013, every retailer and dealer shall display price list and the supplementary price list, if any, as furnished by the manufacturer, on a conspicuous part of the premises where he carries on business in a manner so as to be easily accessible to any person wishing to consult the same.
- (g) Where an existing manufacturer of scheduled formulation with dosage or strength or both as specified in the above table launches a new drug as per paragraph 2 (u) of the DPCO, 2013 such existing manufacturer shall apply for prior price approval of such new drug to the NPPA in Form I as specified under Schedule-II of the DPCO, 2013.
- (h) The manufacturers of above said scheduled formulations shall furnish quarterly return to the NPPA, in respect of production / import and sale of scheduled formulations in Form-III of Schedule-II of the DPCO, 2013 through IPDMS. Any manufacturer intending to discontinue production of above said scheduled formulation shall furnish information to the NPPA, in respect of discontinuation of production and / or import of scheduled formulation in Form-IV of Schedule-II of the DPCO, 2013 at least six months prior to the intended date of discontinuation.
- (i) The manufacturers not complying with the ceiling price and notes specified hereinabove shall be liable to deposit the overcharged amount along with interest thereon under the provisions of the Drugs (Prices Control) Order, 2013 read with Essential Commodities Act, 1955.
- (j) Consequent to the issue of ceiling prices of such formulations as specified in column (2) of the above table in this notification, the price order(s) fixing ceiling or retail price, if any, issued prior to the above said date of notification, stand(s) superseded.